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54. Name of Invention VERTEBRAL BODY SPACER
21. Patent Application Showa 57-31603
65. Public Exhibition Showa 58-149753
22. Application Date February 27, 1982 (Showa 57)
43. September 6, 1983 (Showa 58)

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(p.117, column 1)

## 57. Area covered by the Patent Request

1. A vertebral body spacer that is block-shaped, made of material that is secure and provides affinity inside the body, and is anti-corrosive; has a protrusion at both the top and bottom surfaces; and both the top and bottom surfaces are slanted from the protrusion toward the back, to form a wedge-shape.

## Detailed Description of the Invention

This invention involves substitute bones for transplantation, especially aimed at providing vertebral body spacers which will replace especially the intervertebral disc of the spinal column.

Between the vertebral body of the spinal column is an intervertebral disc that is made of cartilage, which may be removed due to symptoms such as hernia of the intervertebral disc. When this happens, it is necessary to prepare a substitute. Currently, a part of the bone is extracted from another part of the body and transplanted, but this unfortunately requires a separate surgery to extract that bone which is to be transplanted.

This invention aims to provide a vertebral body spacer that will substitute for the intervertebral disc from living bones.

Another goal of this invention is to provide a vertebral body spacer that is simple to set in place, will not slip out of place or come off, and will last a long time.

According to this invention, we can obtain a vertebral body spacer whose characteristic is one that is block-shaped, made of material that is secure and provides affinity inside the body, and is anti-corrosive; has a hole that passes through the front and back; has protrusions at both the top and bottom surfaces; and both the top and bottom surfaces are slanted from the protrusion toward the back, to form a wedge-shape.

(p.117, column 2)

This vertebral body spacer is to be substituted for an intervertebral disc, where the top and bottom surfaces of the vertebral body is placed in opposition to one another; and the front area of the protrusion at both top and bottom should contact the vertebral body surface above and below it in order to maintain the space between the top and bottom vertebral bodies. This spacer is slanted like a wedge toward the back, at both top and bottom; therefore, during implantation, by forming an indentation at the opposing vertebral bodies at the top and bottom, the protruded area of the spacer will fit into this indentation, whereby preventing the spacer from coming out after implantation.

Spacer material come in ceramic, plastic, rubber, and metal; and one can choose that which is secure and provides affinity inside the body, and is anti-corrosive. Representative examples include: for ceramic -- alumina ceramic and phosphoric acid calcium ceramic; and for metal -- titanium, stainless steel, cobalt chrome alloy, and tantalum.

See below for a detailed explanation, with drawings that illustrate an implementation sample of this invention.

In Diagram 1, the indicated vertebral body spacer 1 is, for instance, made of a rough hexahedron block which is shaped from alumina ceramic, and the front surface 2 and back surface 3 are more or less parallel, and a hole 4 passes right through them. At the top and bottom surfaces of this block-shaped vertebral body spacer 1 there are protrusions 5 and 6 on each, which extend from one side to the other. Here, in protrusion 5, the cross section is shaped like a mountain, a rough triangle; and in protrusion 6, the outer shape of the cross-section is either semi-circular, or has some other form of rounded shape. Areas 7 and 8, which are in front of protrusions 5 and 6 at both top and bottom surfaces, are more or less parallel to each other; and areas 9 and 10, which are in back of...

(p.118, column 1)

...protrusions 5 and 6, are wedge-shaped, forming a slant that approaches each other towards the back. Furthermore, both the left and right surfaces, 11 and 12, which are forward with respect to the position of protrusions 5 and 6, are parallel to each other; and rear surfaces 13 and 14 are wedge-shaped, having slanted surfaces that approach each other towards the back.

The following is an explanation of a sample with vertebral body spacer 1, using Diagram 2 and Diagram 3.

First of all, the intervertebral disc 21 at the location where vertebral body spacer 1 is to be applied, as well as vertebral bodies 22 and 23 which are above and below it, should be shaved off a little at a time from the front, to form space 24 that will plug up vertebral body spacer 1. In doing so, it is best to make the shape of space 24 bigger than the outer shape of vertebral body spacer 1, but the outer shape of the front end of the space must match the outer shape of the front part of vertebral body spacer 1 in its proper position, and it is necessary to form indentations 25 and 26 which will receive protrusions 5 and 6.

After forming space 24, expand the space of vertebral bodies 22 and 23 by using a "vertebral body space expander," and insert vertebral body spacer 1 into space 24, with the back surface 3 going in first. In doing so, insert the triangular protrusion 5 into the corresponding indentation 25. Then, when spacer 1 is pushed in from the front, the round protrusion 6 should slide over the back vertebral body 23, and fit into indentation 26.

In this manner, vertebral body spacer 1 should be set in between vertebral bodies 22 and 23, in a condition where the forward space surfaces of the top and bottom vertebral bodies 22 and 23 are contacting the front areas of the top and bottom surfaces of vertebral body spacer 1 (see Diagram 1, 7 and 8), whereby maintaining proper position between the top and bottom vertebral bodies 22 and 23. At the same time, top and bottom protrusions 5 and 6 should be inserted into indentations 25 and 26, whereby preventing vertebral body spacer 1 from falling off in the future. This condition is shown in Diagram 3. Furthermore, the penetrating hole 4 of vertebral body spacer 1 will act as a type of drain that will discharge liquids, such as blood which may leak from the back of the space after implantation, to the front.

Adding texture (linear streaks) 15 and 16 to the surface of the vertebral body spacer, as shown in Diagram 4, will help maintain the connection of the vertebral body spacer surface to the vertebral body and intervertebral disc, due to such changes as...

(p.118, column 2)

...bone recycling and increase after implantation, thus adding to the security and maintenance of the vertebral body spacer.

As for each of the various measurements of the vertebral body spacer, such as the cervical vertebrae, thoracic vertebrae, and lumbar vertebrae, simply make the appropriate choice that corresponds to the measurement of the vertebral body and intervertebral disc of the applicable part.

Above was an explanation of a specific implementation sample of this invention. However, this invention is not limited to this particular implementation sample, but there are many transformations possible. For instance, protrusions 5 and 6 do not necessarily have to be triangular or round, respectively. As long as these act as stoppers after implantation, other shapes may be used. Also, these protrusions do not have to be one continuous line from left to right, but may be several noncontinuous lines, or simple multiple protrusions that are lined up left and right, as long as they achieve their purposes.

Furthermore, the penetrating hole for the drain can be round, or any other shape, and there may be many of them.

Also, the surface of the vertebral body spacer may not necessarily be composed of parallel flat areas 11 and 12, and slanted surfaces 13 and 14, as shown in Diagram 1, but may instead be flat surfaces, or when considering bone proliferation, it may be curved, or even uneven.

As it is clear from what has been explained above, according to this invention, extraction of a bone to be transplanted by means of intervertebral disc surgery becomes unnecessary, and it can be implanted securely by simply placing it in between the vertebral bodies. It will be preserved between the vertebral bodies, and will last a long time after implantation, preventing any off-centering or detachment from occurring between the vertebral bodies.

A Simple Explanation of the Diagrams

Diagram 1 shows one implementation sample of this vertebral body spacer invention: Diagram (a) is a plane view, Diagram (b) is the left surface, Diagram (c) is the frontal view. Diagram 2 shows the vertebral bodies of those parts to which the vertebral body spacer is applied, as well as explains the formation surgery of the intervertebral disc: Diagram (a) is the frontal view, Diagram (b) is the cross-section. Diagram 3 shows the cross-section when the vertebral body spacer is implanted. Diagram 4 shows a diagonal external view of another implementation sample.

1... vertebral body spacer, 2 ... frontal view, 3 ... rear view, 4 ... penetrating hole, 5 and 6 ... protrusions, 7 & 8 ... frontal parallel area, 9 & 10 ... rear slanted area.

M&F0001
Ref. 101.0037-01000

Japanese Laid Open Patent
Application Sho 62-155846

Title of the invention:

Mid spine block used for the lumbar

2. Scope of claims

Claim 1:

An in-spine block used for the lumbar wherein the securing component is formed into a pillar, on which multiple protrusions are formed on the lower surface.

Claim 2:

The in-spine block used for the lumbar of Claim 1 wherein the pillar shaped body is formed of an alumina or abatite (phonetic) ceramic, or the like.

[Official seal] Union of Soviet Socialist Republics

USSR State Committee on Inventions and Discoveries

(19) SU 1107854 A

3(51) A 61 B 17/18

# PATENT CLAIM DESCRIPTION

(21) 3570386/28-13
(22) 30.03.83
(46) 15.08.84, bulletin No. 30
(72) A.A. Korzh, S.D. Shevchenko, N.I. Khvisyuk, G.Kh. Gruntovskiy, Ye.M. Makovoz; I.B. Timchenko, A.G. Golukhova, and V.A. Kutsenko
(71) Prof. M.I. Sitenko Kharkov Scientific Research Institute of Orthopedics and Traumatology
(53) 615.472.616.711-089.843(088.8)

(54)(57) A VERTEBRAL COLUMN IMMOBILIZATION LOCK which consists of a support with restraining elements *is characterized in that* in order to enable correction and stable immobilization of the vertebrae by preventing their rotation in the frontal and sagittal planes, the support is designed as a wedge and is supplied with a connecting serrated lamella.

This invention is in the area of medicine, particularly orthopedics and traumatology, and can be used for surgically correcting deformities and stabilizing the intervertebral joints in the cases of scoliosis, cyphosis, osteochondrosis, and other vertebrae disease.

A vertebral column immobilization lock is known; it contains a parallelepiped-shaped support equipped with immobilizing elements shaped as parabolic protrusions with cutting edges sloping at an angle to the parallelepiped's longitudinal axis.

Yet the aforementioned device cannot correct such deformities as angular misalignments of the bodies of adjacent vertebrae that are typical of scoliosis, cyphosis, and osteochondrosis of the vertebral column. This is due to the fact that the device is designed as a parallelepiped. Furthermore, due to certain design features of the resetting and stabilizing elements, the device can effectively resist only shear loads in the sagittal plane but has no stabilizing effect against the torque action that rotates the vertebrae in the frontal and sagittal planes, i.e., cannot ensure fully immobilized contact between vertebrate in an arthrodesis motion.

The invention objective is to enable correction and stable immobilization of the vertebrae by means of preventing rotation in the frontal and sagittal planes.

The above objective is achieved by designing the vertebrae immobilization restraint support as a wedge equipped with a serrated connecting lamella.

Figure 1 depicts a general view of the device; figure 2—the intervertebral space after installation of the lock (front-to-back projection); figure 3 shows the intervertebral space after installation of the lock (side view).

The vertebral column immobilization lock has intervertebral wedge-shaped support *1* whose load-bearing surfaces have stabilizing "herringbone" elements *2* equipped with connecting lamella *3* made as a channel whose flanges have serrated cutting edges with teeth *4*. The flanges of connecting plate *3* have holes *5* to allow bone tissue grow through them.

The use of the proposed vertebral column correcting lock is demonstrated using the specific example of radical treatment of a patient with a cyphoscoliotic deformity of the intervertebral joint between the fourth and fifth lumbar vertebrae.

While in the operating room, the patient lying on his back is intubated and given endotracheal anesthesia. Using conventional femoroinguinal retroperitoneal access method, the anterior section of the fourth lumbar intervertebral disk and the body of the fourth and fifth lumbar vertebrae are exposed. The pulpal nucleus tissue and inner sections of fibrous ring of the fourth intervertebral disk are removed but without exsection of the elastic plates. To facilitate subsequent immobilizing lock installation, transverse incisions are made in the cortical layer of adjacent vertebrae at a distance from the body edge which corresponds to the distance from the load-bearing surface of the immobilizing lock to the connecting lamella flange.

Then the immobilizing lock is inserted into the intervertebral space using a hammer and an impactor, thus changing the mutual position of adjacent vertebrae into the position that corresponds to the mutual position of the load-bearing surfaces and the height ratio of the anterior and posterior sections of the intervertebral support. Insertion of connecting lamella *3* into the vertebrae body forms secure linkage between the immobilization lock and adjacent vertebrae.

Thus, the innovative design features (wedge-shaped intervertebral support and channel-shaped connecting element) of the proposed correcting immobilization lock ensure optimum anatomic alignment of the adjacent vertebrae bodies while simultaneously stabilizing the arthrodesic segment. Ceramic materials may be used for making the immobilization lock. Thirteen correcting immobilization locks have been fabricated at the institute; they have passed experimental testing and will be used when indicated.

BOKO/ ★ P31 85-183939/22 ★SU 1124-960-A

**Endo-osseus analysing puncture instrument - comprises first needle holding second needle, with serrated cutting edge on working end and cannula on the other**

BOKOV N F 19.02.80-SU-888097

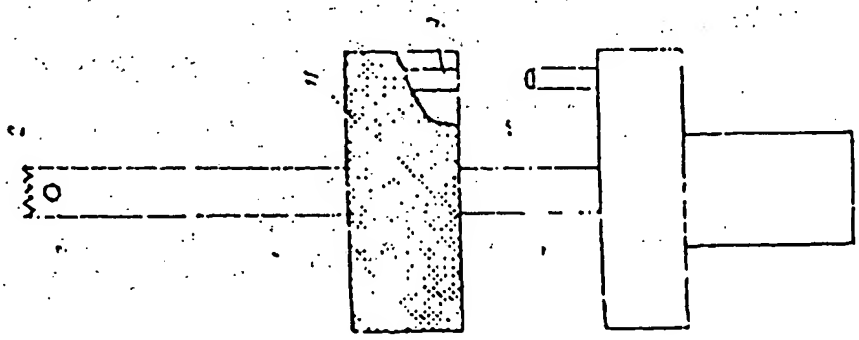
*(23.11.84) A61b-17/34*

19.02.80 as 888097 (1462AS)

The instrument has two cylindrical tubular needles (1,2) each with serrated working end and canula on the other end. The second needle (4) is positioned inside the first needle (2). The splices of the serrations of the needles (1,4) are positioned in the same plane perpendicular to the longitudinal axis. The outline of the serrations of needle (4) is similar to the outline of the serrations of needle (1). The first needle (1) has two coaxial side apertures (7) in its working end, and the working end of second needle (4) has two grooves opposite each other. Outer needle (1) has an aperture (9) and inner needle (4) a pin (10) for the mutual fixation of needles (1,4).

USE - To take a bone marrow bio-optate and perform interosseous diagnosis and introduce medicinal substances using the same instrument. Bul.43/23.11.84 (3pp Dwg.No.1/2)

N85-100571



SEIS = ★ P31 86-296893/45 ★SU 1217-374-A

**Endoscopic knife - equipped with stop, and having shaped cutting edge made as teeth or spiral positioned at angle to axis**

SEISMOLOGY INST(CLIN = ) 03.02.84-SU-698949

*(15.03.86) A61b-17/32*

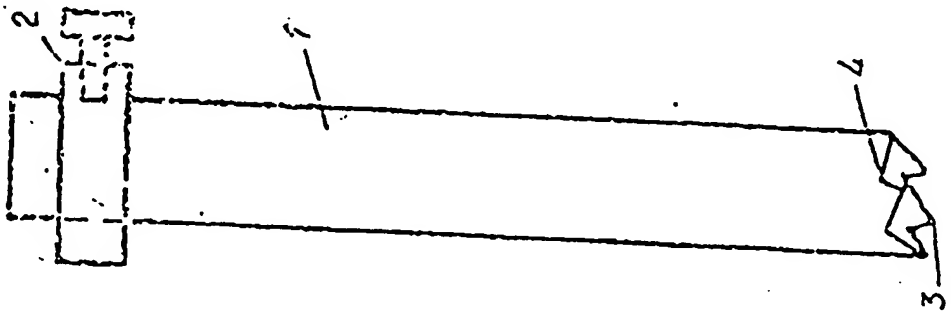
03.02.84 as 698949 (1549MB)

The proposed knife is equipped with stop (2). The cutting edge is at an angle to the axis, and is designed shaped. It is designed in the form of unequal-sided teeth (3), with the cutting edges on long side (4), in the form of a curvilinear spiral.

The knife is put onto the viewing hood of a bronchoscope, and is moved forward. The depth of penetration of the knife is controlled by stop (2). The scar excrescences are cut off with the cutting edge. Stop (2) allows the centring of the knife in the lumen of the hollow organ.

USE/ADVANTAGE - For removing neoplasms from tubular organs. Reduces traumaticity with circular resection of the tissues on the internal walls of internal organs by enabling visual control through bronchoscope. Bul.10/15.3.86 (2pp Dwg.No.1/2)

N86-221741



BOGO/ ★ P31 P34 86-324157/49 ★SU 1222-254-A

**Intra-osseous infusion needle - featuring tube cutting part as recurved teeth, and middle tube part with thickening**

BOGOSYAN A B 09.11.83-SU-660510

*(07.04.86) A61b-17/16 A61m-05/32*

09.11.83 as 660510 (1549MB)

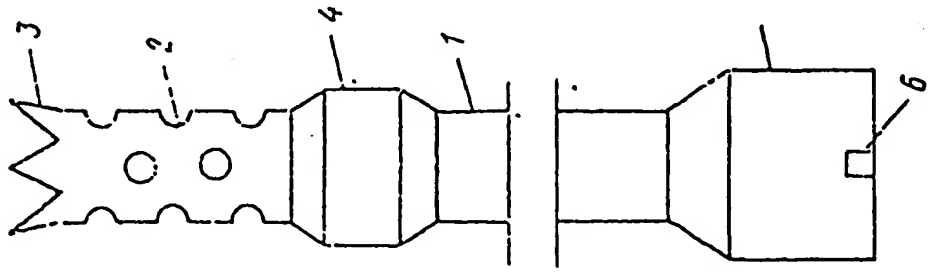
The cutting part of tube (1) of the proposed needle is designed in the form of teeth (3), recurved from the longitudinal axis. The middle part of tube (1) has thickening (4). The dia. of the thickening (4) is greater than the dia. of the cutting part.

The bone is trephined with the operative end of the needle. When moving the needle farther, the pointed end of the mandrin cracks and moves apart the osseous structures. Teeth (3) grind the structures, forming bone chips. The thickening (4) collects the chips in front and fills the gap between the bone and the thickening. The infused liquid accumulates around the needle and penetrates to the little damaged interonsseous spaces.

ADVANTAGE - Preserves the bone chips in the osseous channel.

Bul.13/7.4.86 (2pp Dwg.No.1/1)

N86-241623



**Swedish Patent No. 106 101**

Title: *System with Apparatus for Driving Together Brackets, Splinters, Pins, or the Like*

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Claim 1: System with such apparatus for driving together brackets, splinters, pins or like fastenings of unlike dimensions, which consists of a hole with a forward and backlying [punching organ] for driving together fastenings, which consists of a hole (1) with several similar or unlike dimensioned guiding channels (6, 7, 8, 9 in Figure 5) for [taking up] of brackets and or also with both one or more such channels (6 in Fig. 2, resp. 6, 7 in Fig. 3, resp. 6, 7, 8 in Fig. 4, resp. 6, 7, 8, 9 in Figure 6 and 7) and one or more for splints, or pins offsetting openings (10 in Fig. 2, 3, 6, and 7, resp. 10, 11 in Fig. 4) with other dimensions than the channel respectively, the channel together with a [punching organ] (2) being formed in accordance herewith.

101.0042-00PCT

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03770

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70
US CL :227/19, 147, 175; 606/61, 75, 96, 99; 623/17
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 227/19, 147, 175; 606/60, 61, 69, 71, 72, 75, 96, 99; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US, A, 4,913,144 (DEL MEDICO) 03 April 1990, see entire document. | 1, 7-11 |
| X<br>---<br>Y | US, A, 4,960,420 (GOBLE ET AL.) 02 October 1990, see column 6 lines 3 and 4, and figure 6. | 33, 36, 38, 46-48<br>---<br>5, 6, 15, 16, 39, 40, 49, 50, 51 |
| X, P | US, A, 5,364,399 (LOWERY ET AL.) 15 November 1994, see entire document. | 33-35 |
| Y | US, A, 4,570,623 (ELLISON ET AL.) 18 February 1986, see entire document. | 5, 6, 39, 40 |

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" | document defining the general state of the art which is not considered to be part of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

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|---|---|
| Date of the actual completion of the international search<br>07 JUNE 1995 | Date of mailing of the international search report<br>03 JUL 1995 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>Stacia Sinnik for<br>TAMARA L. GRAYSAY<br>Telephone No. (703) 308-0858 |

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03770

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US, A, 350,420 (J. W. DILLON) 05 October 1886, see entire document. | 17-19 |
| A | US, A, 4,903,882 (LONG) 27 February 1990, see entire document. | 17 |
| A | SE, A, 106,101 (K. R. L. GRAUDING) 08 December 1942, see entire document. | 17 |
| A | US, A, 2,181,746 (J. R. SIEBRANDT) 28 November 1939, see entire document. | 23 |
| A | US, A, 4,570,624 (WU) 18 February 1986, see entire document. | 23 |